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To cite this article: Ronald W. McLeod & Paul Bowie (2018) Bowtie Analysis as a prospective risk assessment technique in primary healthcare, Policy and Practice in Health and Safety, 16:2, 177-193, DOI: [10.1080/14773996.2018.1466460](https://doi.org/10.1080/14773996.2018.1466460)

To link to this article: <https://doi.org/10.1080/14773996.2018.1466460>



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Published online: 09 May 2018.



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Bowtie Analysis as a prospective risk assessment technique in primary healthcare

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ABSTRACT

Despite repeated calls for the use of proactive assessment of serious significant events in primary healthcare, GP teams in the UK rarely apply the kind of formal methods of prospective risk assessment that are commonly used in high-hazard industries. NHS Education for Scotland (NES) conducted an exploratory workshop to assess the potential value of Bowtie Analysis (BTA) as a means of proactively identifying and assessing the controls relied on to protect against the risk of a potential primary care 'never event'. It was concluded that BTA could provide a straightforward approach to engage frontline care practitioners and managers in proactively assessing risk. However, concerns remain about the level of training, support and resources that would be required for the healthcare community to be capable of conducting BTA to an adequate quality standard without having to rely on external facilitators.

ARTICLE HISTORY

Received 6 February 2018

Accepted 16 April 2018

KEYWORDS

Bowtie analysis; prospective risk analysis; general practice; primary healthcare; never events

Introduction

Primary healthcare relies on a wide variety of measures to control against the occurrence of events with the potential to impair the health and/or safety of patients. Formal controls include assurance of the professional qualifications and licensing of health professionals, the use of clinical guidelines and protocols to support diagnosis and prescribing, and requirements for independent cross-checking of prescriptions, medications, and recommended courses of treatment. Informal controls can range from expectations that clinicians or supporting staff – or even patients themselves – will notice errors or discrepancies in patient records, medication prescriptions, or the implementation of management system elements (such as procedures for checking emergency drugs or ensuing equipment is in compliance with standards and regulations). Informal controls include expectations that key lessons from incidents will be accurately captured, shared and applied in future, and assumptions that service providers will not be unintentionally motivated or incentivized to cut corners or adopt unsafe practices.

In its guidance on assessing clinical risk, NHS England (NHS, 2007) emphasized the importance of identifying and managing controls: 'For each hazard identified, it is important to decide whether ... appropriate and sufficient controls or contingencies are in place to ensure that the risk is properly controlled' (p.4). However, in healthcare controls are rarely subjected to formal scrutiny or assessment to determine whether they are as effective as is believed, whether they are actually in place and functional, or under what conditions they can fail. In contrast, what are often described as the 'high-hazard' industries – such as nuclear power, chemical manufacturing, oil and gas, aviation, air traffic management, rail, and shipping

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– go to significant lengths not only to identify the hazards associated with their activities, but to ensure they have controls in place that are sufficiently effective and reliable to reduce risk to a level that is considered tolerable.

This paper reviews the potential value of Bowtie Analysis (BTA) as an approach to prospectively identifying and managing risk in primary healthcare. The paper is in two parts. The first introduces the key concepts in BTA, reviews relevant literature, and discusses some theoretical background to the method. The second part reports an informal evaluation conducted by NHS Education for Scotland (NES) to explore the potential benefits that may be gained from BTA if it was used in primary healthcare. In contrast with nearly all previous published studies, the workshop was conducted in accordance with new industry guidance on best practice in BTA (CCPS, in press; CIEHF, 2016). In particular, the workshop (i) applied widely accepted quality criteria to determine whether controls relied on to protect against primary care events could be considered ‘barriers’ in the sense the term is used in high-hazard industries, and (ii) used the constructs of BTA to explore in some depth the ways in which main barriers can be defeated or degraded, and the safeguards that need to be in place to protect against such degradation.

Bowtie Analysis

The rapid growth in the use of BTA as a risk management tool in recent years has been driven largely by what is seen as the conceptual simplicity of the approach and the visual representation of the analysis, together with the availability of off-the-shelf and easy-to-use software tools (CCPS, in press; de Ruijter and Guldenmund, 2016).

Bowtie Analysis has suffered both from lack of a strong theoretical foundation and scientific evidence demonstrating its validity as an approach to risk identification and hazard management. Until recently, there has also been a lack of any recognized industry agreement defining what constitutes ‘good’ practice in its use. The Center for Chemical Process Safety (CCPS, in press) has recently published the first generally agreed statement of what constitutes good practice in conducting and using BTA in the global oil and gas, chemical, and process industries. The UK’s Chartered Institute of Ergonomics and Human Factors (CIEHF) has published guidance on good practice in dealing with human and organizational factors in barrier management in general, and Bowties Analysis in particular (CIEHF, 2016).

Bowtie analyses are usually conducted based on some activity or operation where there is known to be the potential for harm. The diagrams prepared to represent the results of an analysis comprise a number of elements, as illustrated in Figure 1.

- Each diagram is associated with a specific hazard, i.e. a source of energy or activity with the potential to do harm.
- For each hazard, diagrams are developed for a single ‘top event’ – one of the ways in which the hazard could be released. In principle, there can be multiple top events – and therefore multiple Bowtie diagrams – for a single hazard. (Note: the term ‘top event’ reflects the roots in Fault Tree Analysis, where the unwanted event is visually located at the top of the page, with failures with the potential to lead to the event represented lower down.)
- Threats are events that, if they are not prevented from doing so, are likely to lead to the top event occurring.
- Barriers are the defences against the threat: on the left-hand side of the Bowtie, they reduce the likelihood of the threat leading to the top event. On the right-hand side, they prevent a top event, if it did occur, from leading to the consequences¹. Barriers in principal may comprise both technical (i.e. engineered) and human elements.
- Degradation factors are things that could cause a barrier to fail to do its intended job.
- Safeguards are things that are intended to prevent the degradation factors from interfering with the functioning of the barrier.

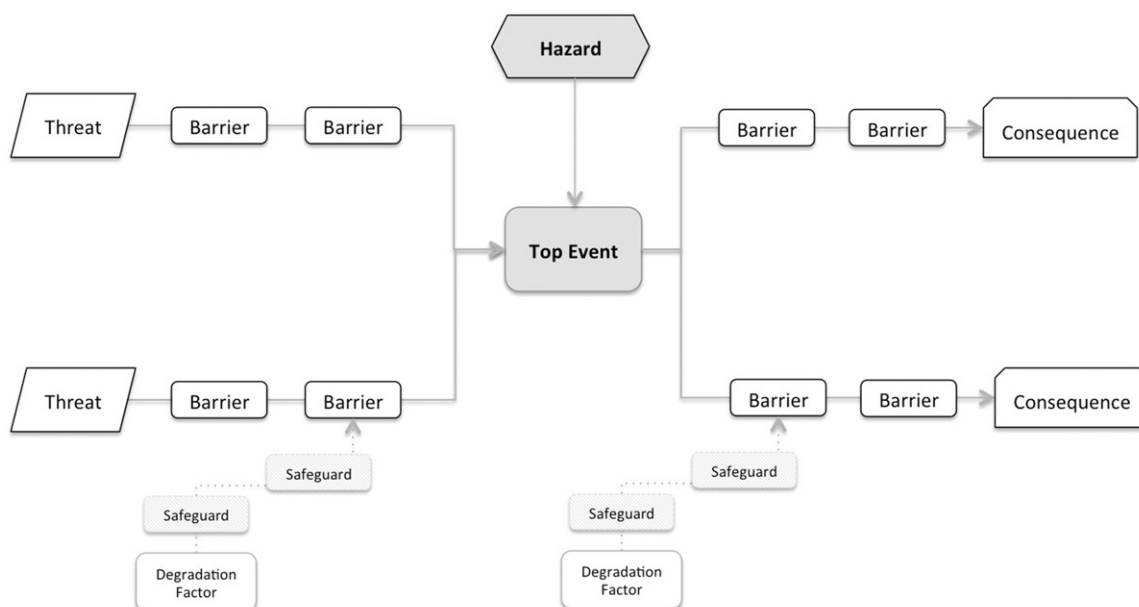


Figure 1. Elements of a Bowtie Analysis.

Types of controls: barriers and safeguards

In BTA, the term ‘barrier’ refers to those controls that can be relied on to protect against the occurrence of the top event. The term is reserved for controls that have been assessed and assured as being sufficiently effective and robust: provided they are properly implemented and maintained relied on to protect against major incidents – they are ‘barriers’. The Centre for Chemical Process Safety (CCPS, in press) defines barriers as: ‘A control measure or grouping of controls that on its own can prevent a threat developing into a top event (prevention barrier) or can mitigate the consequences of a top event once it has occurred (mitigation barrier). A barrier must be effective, independent, and auditable’ (p.xi). At least these three quality criteria (independence, effectiveness, and audibility) – and sometimes six or more – need to be met for a control to be considered as a full barrier (CCPS, in press; CIEHF, 2016).

Barriers can be either active or passive. Active barriers must meet three capabilities: (i) able to *detect* the existence of a threat; (ii) able to *decide* what needs to be done; and (iii) able to take the necessary *action* to block the threat. Passive barriers by contrast provide protection by their physical presence in a situation where a hazard exists.

Active barriers commonly rely on a number of different ‘elements’ working together to deliver the functionality needed to detect, decide, and act. For example, a condom on its own (once it is in place) would be an example of a passive barrier against sexually transmitted diseases and unwanted pregnancy. Though the real barrier is active, comprising two elements working together: (i) human awareness of the need for protection (the detect function) and making the decision to use a condom (the decide function), and (ii) the condom itself providing the actual physical barrier (the act function).

Many, perhaps in a healthcare context the majority, of controls – and especially those that rely on people – cannot meet the quality criteria to be considered as full ‘barriers’. Controls that do not meet the criteria, but nonetheless play an important role in protecting against incidents, are often referred to as ‘safeguards’ (CIEHF, 2016)²; they are important – indeed, they frequently play a central role in safety management systems – but they cannot achieve the criteria required for full barriers. A key output from BTA is clarity about what the real barriers are in any hazardous situation, and what are, in fact, safeguards.

Finally, a comprehensive BTA brings recognition of (i) who is responsible for the state of barriers; (ii) what needs to be done to have confidence that intended barriers are actually in place and effective; and (iii) through the identification and analysis of degradation factors, what can lead to barriers failing to perform as expected, and what needs to be in place to prevent barrier failure.

The theoretical basis of Bowtie Analysis

There is confusion in the technical literature about the theoretical basis of BTA. Assumptions are frequently made, based on the visual structure of the representation, that BTA assumes a linear, event-driven model of accident causation. A type of model that leading thinkers have long argued is inadequate as a means of understanding the dynamics of modern complex socio-technical systems or the ways they can lead to loss (Hollnagel, 2012; Leveson, 2011; Perrow, 1999).

It is, however, important to recognize that in adopting the concepts and structures of BTA, there is no necessity to make assumptions about the mechanisms and processes that lead to incidents. This is one of the most significant differences between BTA and techniques such as Failure Modes and Effects Analysis (FMEA), Event Tree Analysis (ETA), and Root Cause Analysis (RCA). Such techniques explicitly assume that adverse events can be modelled as a sequence of linear relationships and causal interactions between system elements. Not having to rely on such an assumption is one of the principal features that could make BTA more suitable for use in many healthcare settings than other hazard analysis techniques. This is particularly the case where there is both tight coupling and high interactivity between elements of the clinical context surrounding patient care (Marks & Mazur, 2015; Perrow, 1990).

It is true that many users of BTA do subscribe to a traditional linear, event-driven model of technical systems and how they fail. It is also true that BTA has been used in ways that directly, indeed sometimes explicitly, sought to identify and assess barriers that are capable of blocking what is modelled as a linear chain of events between underlying causes and top events (de Ruijter and Guldenmund, 2016; Wierenga et al., 2009). Such assumptions, however, are not necessary. BTA, and the understanding of barriers, failure mechanisms, and safeguards that it can generate, is neutral in terms of any underlying model of accident causation. It need make no assumption about the mechanisms that might lie on the path between threats and the top events and consequences they can lead to. There is no reason why a bowtie model should not be based on a STAMP (Leveson, 2011) or FRAM (Hollnagel, 2012) analysis. For example, if a FRAM analysis raised concern about resonance between functions in the financial services system (Sundström and Hollnagel, 2011), a BTA would identify controls capable of detecting signs of the developing resonance and intervening to dampen them. The threat in this instance would be the unwanted resonance between two or more of the functions. The BTA would also evaluate the quality of the controls to ensure they were capable of providing the protection expected, and would explore how they might fail.

In addition, note that the core BTA method does not include quantifying the likelihood of any barrier failing when it is needed. Some users of the technique have included quantifying the risk of barrier failure within BTA by combining a Fault Tree Analysis (on the left-hand side of the top event) and an Event Tree Analysis (on the right-hand side). de Ruijter and Guldenmund (2016) discuss the difference between quantitative and qualitative uses of BTA. Neither the CCPS (in press) nor the CIEHF (2016) recommend using BTA to quantify the risk of barrier failure.

In summary, when it is performed properly, BTA can provide a rich understanding of the controls that are expected to be in place to protect against incidents, how they can fail, and how they need to be implemented, supported, and managed. In addition, it can do so without having to make any assumptions about the mechanisms or nature of accident causation.

Previous uses of Bowtie Analysis in healthcare

Till date, there have been few published attempts to apply BTA to healthcare. In their major review assessing risks in pharmacy, Phipps et al. (2010) suggested that BTA has a potential value through its

incorporation of concepts drawn from a variety of risk analysis methods, including Root Cause Analysis, Failure Modes and Effects Analysis and the 'Swiss Cheese' model of accident causation.

Kerckhoffs et al. (2013) reported the use of a BTA to assess risk associated with critical events in an intensive care unit. Drawing on a multi-disciplinary team of medical staff, Kerckhoffs et al. generated nine bowtie diagrams covering three hazardous situations. Their analysis identified a total of 84 'barriers' that were not currently implemented, and led to 37 recommendations for improvements. With respect to the 84 missing barriers, they noted that 'these barriers were not thought of when protocols were composed or were not part of the usual care' (p. 158).

It is worth noting that Kerckhoffs et al. did not use any quality criteria to what they considered as barriers: under the bowtie terminology defined by the CCPS and CIEHF most, if not all, of the barriers Kerckhoff et al. identified would be considered as safeguards (or degradation factor controls in CCPS terminology). Nevertheless, their use of BTA was clearly thought to have led to improvements in patient safety in the ICU context.

The Kerckhoffs et al. study included gathering feedback about the usefulness of BTA. Team members, especially valued the structured analysis and appreciated the multi-disciplinary approach and the ability to think 'out-of-the-box' about potential new barriers. It was also noted that both the analysis needed significantly less time and effort than the alternative Healthcare Failure Mode and Effects Analysis (HFMEA) and that it could be conducted without bringing in a specialist external facilitator.

Abdi et al. (2016) also reported on a BTA conducted as a means of proactively identifying and managing clinical risks in intensive care. In their study, a multi-disciplinary team developed bowties for five hazardous situations in ICU. To provide a comprehensive assessment of the major risks in ICU, Abdi et al. adapted the basic BTA method to include risk assessment and prioritization.

Wierenga et al. (2009) adopted an explicit causation model in their assessment of BTA for the prospective analysis of risk in the medication process in a hospital setting in the Netherlands. They focused on three top events associated with management of medication. Their evaluation showed that the bowtie method was well received and seemed well suited as a means of proactively assessing and evaluating risk.

Chatzimichailidou et al. (2017) compared the potential value of BTA and the Systems-Theoretic Process Analysis (STPA – Leveson, 2012) method as approaches to reducing the risk of guidewires being left in place during fitting of catheters. They recognized that, at the time of conducting the research, there was no fully consistent approach available defining how to conduct BTA. Nevertheless, the approach they took and the analysis they developed differs significantly from previous uses of BTA, whether reported in the published literature or as used in industry.

As one example, rather than identifying threats – which has been one of the basic elements of BTA since its inception – on the left-hand side of the bowtie diagram, Chatzimichailidou et al. instead identified a series of 'contributing factors' that might increase the likelihood of the event. In normal bowtie usage, threats refer to events that, if not prevented by barriers, have the potential to lead directly to occurrence of the top event (note that Chatzimichailidou et al. also refer to the top event as their 'initiating event'). Furthermore, few if any of their 'contributing factors' are equivalent to threats. Rather, the contributing factors they identified are equivalent to what would be considered degradation factors. And the 'preventative controls' they identified to limit the effect of the 'contributing factors' are equivalent to what would normally be considered to be controls preventing the degradation factors from defeating or degrading barriers (i.e. safeguards). The paper does not actually identify any of the barriers that a BTA would normally seek to identify as being capable of preventing threats from leading to the top event, or from the top event from escalating to consequences.

More fundamentally, the Chatzimichailidou et al. study showed no recognition of the nature of barriers as they are normally used in BTA. In normal bowtie usage, a 'barrier' is something that provided it functions as expected, and even if every other control on the same threat line fails, is capable of preventing the threat from leading to the top event. Chatzimichailidou et al. did not adopt any of the quality criteria (such as independence, effectiveness, and auditability) normally used to determine whether any of the controls identified could be considered as genuine barriers.

Despite these limitations, Chatzimichailidou et al. found that the BTA they conducted provided valuable insight to means that could be put in place to reduce the risk of guidewire retention events. They also concluded that BTA complemented the use of the STPA method and recommended the use of multiple complementary approaches to assessing the risk of serious hazardous events in healthcare.

In summary, although there have only been a few previously published studies, feedback about the use of BTA in healthcare has been positive in terms of the ease of use and insight generated into what needs to be in place to mitigate risk of serious adverse events.

It is important to recognize that each of the reported applications till date has deviated, often in significant ways, from what is considered good practice in BTA in the traditional high-hazard industries. Most importantly, the term ‘barrier’ has been used loosely, and quality criteria for what is considered as a barrier have not been used in any previous study. Rather, the term barrier has generally been used to refer to any form of activity or procedure that is thought or hoped to play some role either in preventing adverse events, or in mitigating the consequences of those events if they do occur. Furthermore, there has been little if any attempt in the published literature to formally identify and assess the degradation factors that can lead to barrier failure or to understand what needs to be in place to prevent such degradation.

Finally, previous uses of BTA have usually attempted to cover the full scope of prospective risk assessment, up to and including assessing and prioritizing risks. In addition, they have usually been based on an assumption of linear causality between threats and adverse events.

Although it does not use BTA, a particularly interesting use of the concept of ‘safety barriers’ in healthcare is reported by Mazur et al. (2015) in the context of radiation oncology. Mazur et al. report on an analysis of the event learning program (also known as the ‘good catch’ programme) running in their department at the University of North Carolina. On the basis of an analysis of 560 events (including events reaching patients, near misses and unsafe conditions) reported by departmental staff over a nearly 2-year period, Mazur et al. were able to calculate the utility of the various ‘safety barriers’ built into their clinical processes (such as treatment planning and approval, quality assurance checks, and treatment checks). By calculating the ratio of the number of events caught at each step of the processes to the number of events presented to that step, they were able to put a numerical value on the performance of the safety barriers at each step. The ability to evaluate the effectiveness of their safety barriers in this way, however, was dependent on the years of effort that had been put into developing a culture of Continuous Quality Assurance and learning in the department. It was also dependent on having a clear process map of all of their clinical practices.

NES assessment workshop

Recognizing the need for healthcare to improve the way it proactively identifies and manages risk (NHS, 2007), NES was interested in understanding more about the implications if the BTA method was adopted as an approach to prospective risk management in primary healthcare in Scotland. There were thought to be at least five potential benefits:

- Improved recognition and understanding of the controls that need to be in place to protect against the occurrence of major adverse events;
- Raised awareness across the healthcare community and stakeholders of the quality and effectiveness of those controls;
- Understanding what factors can lead the controls to fail and what needs to be in place to protect against such failure;
- Knowing which organizations, bodies, or professional roles in the healthcare community are responsible for implementing, supporting, and maintaining the controls;
- Awareness of how the decisions and actions of different organizations, bodies, or professional roles have the potential to cause controls to fail to protect against the adverse events.

Table 1. Summary of workshop participants' clinical role and experience.

Clinical role	Years of experience
GP 1	25
GP 2	15
GP 3	5
GP 4	5
Practice manager 1	15
Practice manager 2	15
Patient safety manager	25
Patient safety researcher	15

Although the potential benefits are clear, there are also concerns about the practicality and logistics involved in adopting BTA in healthcare. Not least of these are the effort, resources, and skills needed to conduct an analysis. In particular, to be a realistic option as a proactive approach to risk analysis in a healthcare context, the method should be applied by the existing healthcare community with available resources and with minimal reliance on external specialist support.

An exploratory, informal one-day workshop was, therefore, convened with the aim of better understanding whether the potential benefits of BTA were indeed realistic. (Assessment of the concerns over training and resourcing is the subject of a subsequent study.) This section reports on the results of the workshop and demonstrates the nature and level of detail of information that can be generated.

Participants

The workshop was attended by four general practitioners and two practice managers, together with two NES patient safety researchers/ergonomists. Table 1 summarizes the roles and experience of the attendees. Attendance was voluntary, based on responses to an email sent to an NES mailing list (for general practitioners and practice managers) and availability to attend. Given the exploratory nature of the work and the self-selection of the attendees, and as the study was judged to be a service evaluation rather than research, no ethical approval was sought prior to conducting the workshop.

Method

For the purpose of the evaluation, the workshop was facilitated by an external specialist with deep understanding of developing best practice in BTA and experience in its application in industrial contexts. (Note: reliance on an external facilitator is discussed in the limitations section.)

Following an introduction on the purpose of the study by a NES patient safety researcher/ergonomist, the facilitator gave a 40-minute presentation on the BTA method, including examples of how it is used in high-hazard industries. The facilitator then led the attendees through the BTA in five steps as follows:

- i. Identification of the controls that were thought to be in place to protect against the never event;
- ii. Identification of possible threat scenarios and realistic consequences if the never event did occur;
- iii. Evaluation of the suggested controls against barrier quality criteria (see below);
- iv. Identification of potential degradation factors;
- v. Identification of safeguards that could protect against barrier degradation (including both safeguards currently known to be in use and those that, in principle, could block the degradation factor).

Being exploratory in nature rather than a formal evaluation, attendees were encouraged to ask questions and to comment on anything they found unclear or that lacked relevance to their work. Once the basic bowtie structure was identified (threats, top events, consequences, and barriers), decisions about

which degradation factors to explore were made by the facilitator, taking account of the time available and the experience and interests of the attendees.

A spreadsheet showing the information recorded by the facilitator was displayed on a screen so that all attendees could view what was being documented. No other record was made of the workshop.

Top event and hazard

A potential primary care ‘never event’ (de Wet et al, 2014; Department of Health, 2011) was selected as the basis of the analysis: ‘Prescribing systemic oestrogen-only hormone replacement therapy for a patient with an intact uterus’. According to Stocks et al. (2017), this event has been estimated to have occurred at least once in the previous year by 37/501 General Practitioner respondents (7%), with 159/556 (29%) estimating that it will likely occur in the next five years in their practices.

The hazard in this situation is the physiological/biochemical mechanism leading to the development of cancer of the womb. The selected never event was treated as the top event. Note that while equating the never event with the top event may seem obvious; it is not necessarily the case that never events should be equated with top events. As a general principle, top events should be selected that lie as far to the left-hand side of the bowtie model as possible (CIEHF, 2016). The rationale is that the further towards the left the top event is located, the more space, in terms of time and opportunity, is created to detect and react to the event before it leads to one of the identified consequences. There can also be significant differences between the nature of the controls – including the reliance on the competence, skills, and the ability of the individuals involved to make judgments and take decisions in what can be stressful and time-critical situations – likely to be used on the left- and right-hand sides of the top event. In practice, top events need to be sufficiently serious in their own right that any competent and aware professional with the relevant responsibility (in this case GPs) would, if they knew about its occurrence, recognize its seriousness and intervene without having to be prompted.

In the time available, the workshop concentrated only on one of the three potential threat scenarios that could lead to occurrence of the top event: an existing female patient attending for hormone replacement therapy (HRT). Five possible consequences were identified as potentially arising from the occurrence of the never event (Figure 2).

Identification of barriers

Participants initially suggested nine controls expected to be in place in GP practices in Scotland to prevent the occurrence of the selected never event. In order to be considered as a barrier, the suggested controls were evaluated against the six quality criteria suggested by the CIEHF (2016):

- Having a clear owner within the local organization;
- Being traceable to some requirement in the local management system;
- Being specific to the threat;
- Being independent from other controls protecting against the same threat;
- Being effective (i.e. provided it functions as expected, each control on its own, if all other controls fail, should be capable of blocking the threat);
- Being auditable.

A review of the proposed controls against these six criteria concluded that only three of them could meet all six criteria and could, therefore, be considered as full barriers, and that two of them comprised multiple barrier elements:

1. Use of the electronic patient record system, comprising the elements;
 - a. Health records database

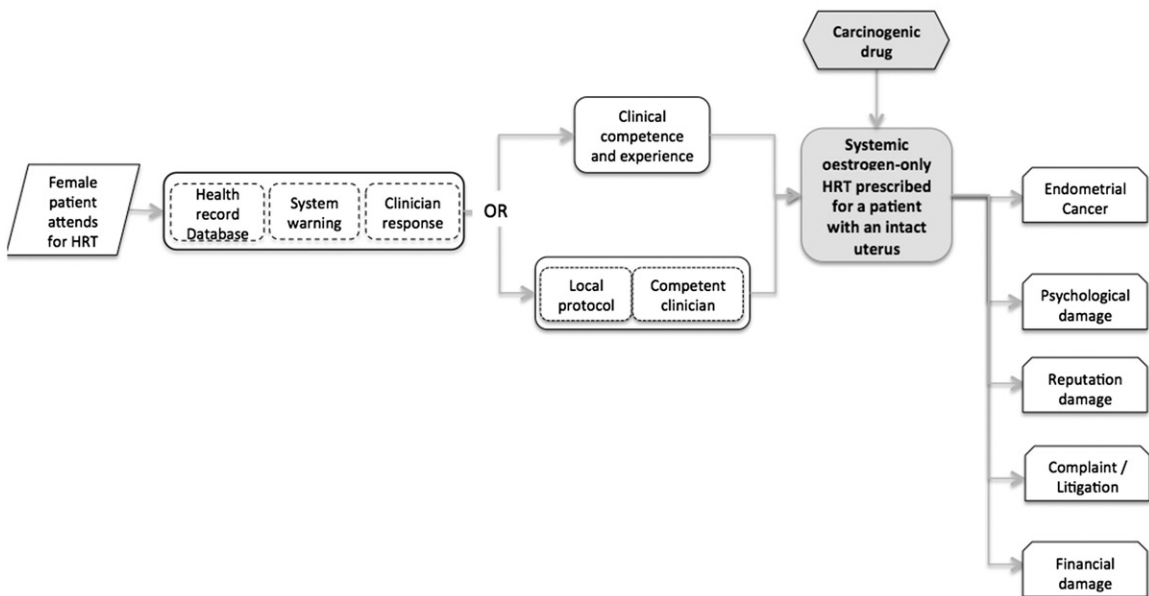


Figure 2. Top-level bowtie showing protective barriers.

- b. A system-generated warning specific to the never event
 - c. Effective clinician response to the warning
2. Use of a local protocol, comprising the elements;
 - a. A local protocol specific to the never event
 - b. Clinician competence to understand and use the protocol
3. Clinician competence and experience.

Figure 2 shows the left-hand side of the top-level bowtie diagram developed for this never event. The figure shows the three preventive (left-hand side) barriers and the elements needed to deliver the functionality for two of the barriers.

Note that, as indicated in Figure 2, the second and third of these barriers are mutually exclusive. In one case, the GP uses a protocol to support their competence, whereas in the other a protocol is not used and the GP relies exclusively on their knowledge and experience. Because they both include competence of the clinician as an element, they cannot exist simultaneously as independent barriers.

Degradation factors and safeguards

Figure 3 shows the degradation factors identified for each of the barriers shown in Figure 2 and shows which of the barrier elements can potentially be made ineffective by each of them.

The workshop then considered what safeguards could be effective in preventing each of the degradation factors from leading to partial or complete failure of each barrier or element. As an example, Figure 4 shows the identified safeguards associated with degradation of the barrier 'Electronic patient record system'. Full details for this barrier are summarized in Table 2.

Fourteen of the identified safeguards were considered aspirational: they could in principle protect against degradation of the barriers but are not currently in widespread use (if they are in use at all). Although the others should be in current practice, it was not clear whether those responsible for implementing or performing them recognize the critical role they play in protecting against the never event.

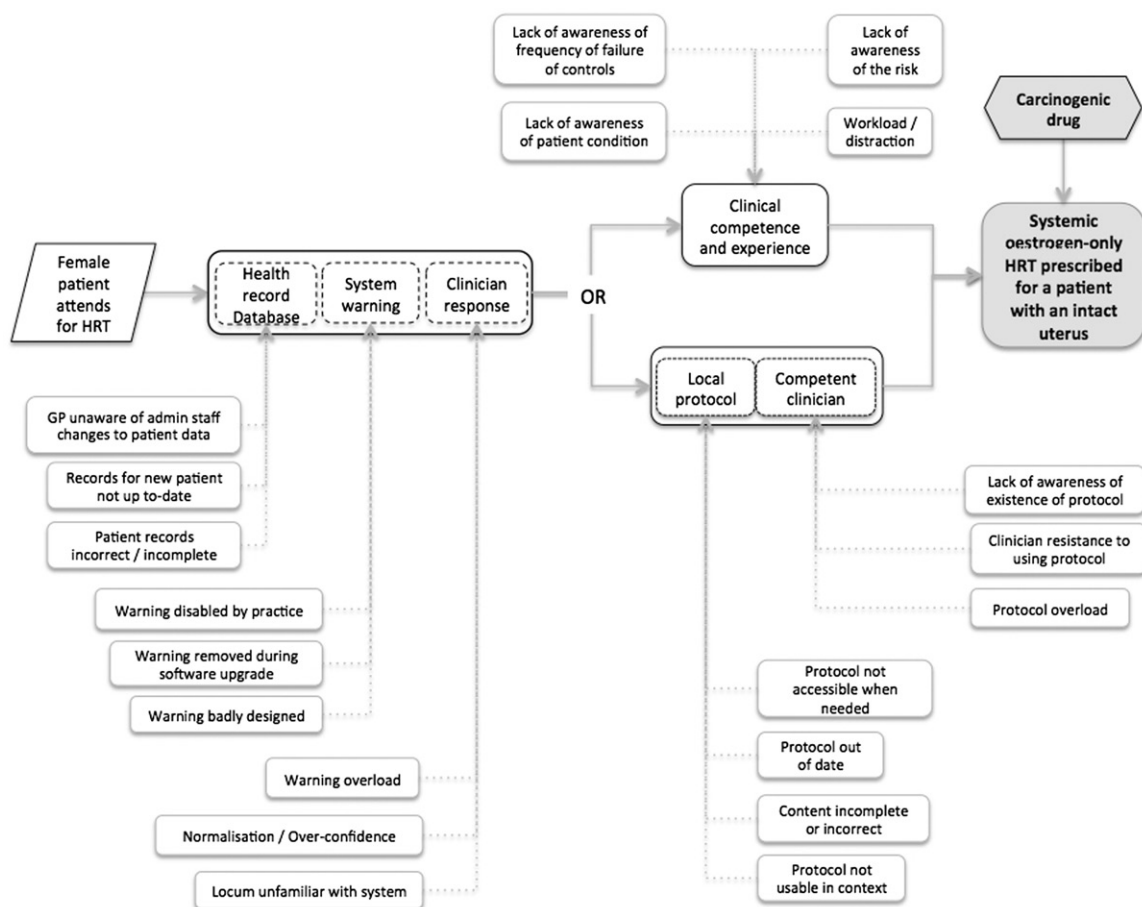


Figure 3. Left-hand side of bowtie diagram showing degradation factors associated with each of the protective barriers.

Workshop evaluation

Being exploratory in nature, the workshop did not attempt to conduct a formal assessment of delegate's reaction to the potential for BTA to be used as a prospective risk assessment method in primary health-care. Evaluation was based on comments and discussion at the workshop, as well as the feedback received following delivery of the workshop report. Overall, there was a positive reaction to the workshop and a general consensus that primary healthcare could benefit by making use of the BTA method more widely. A number of conclusions were drawn as follows:

- Attendees found the process clear and understood what was asked of them. None reported feeling the need for training in order to contribute to the analysis.
- Some of the terminology used in BTA (such as 'threats', 'hazards', and 'top events') is not intuitively clear. Some customization, as well as specific training, may be needed to make the concepts suitable for application in a healthcare context.
- The material generated was considered to be of practical relevance to the management of the selected never event.
- The visual presentation of the results was found to be useful and easy to understand.
- A number of the attendees felt that they had learned about what needs to be in place to control against the risk of the selected never event, and/or how the never event could occur.

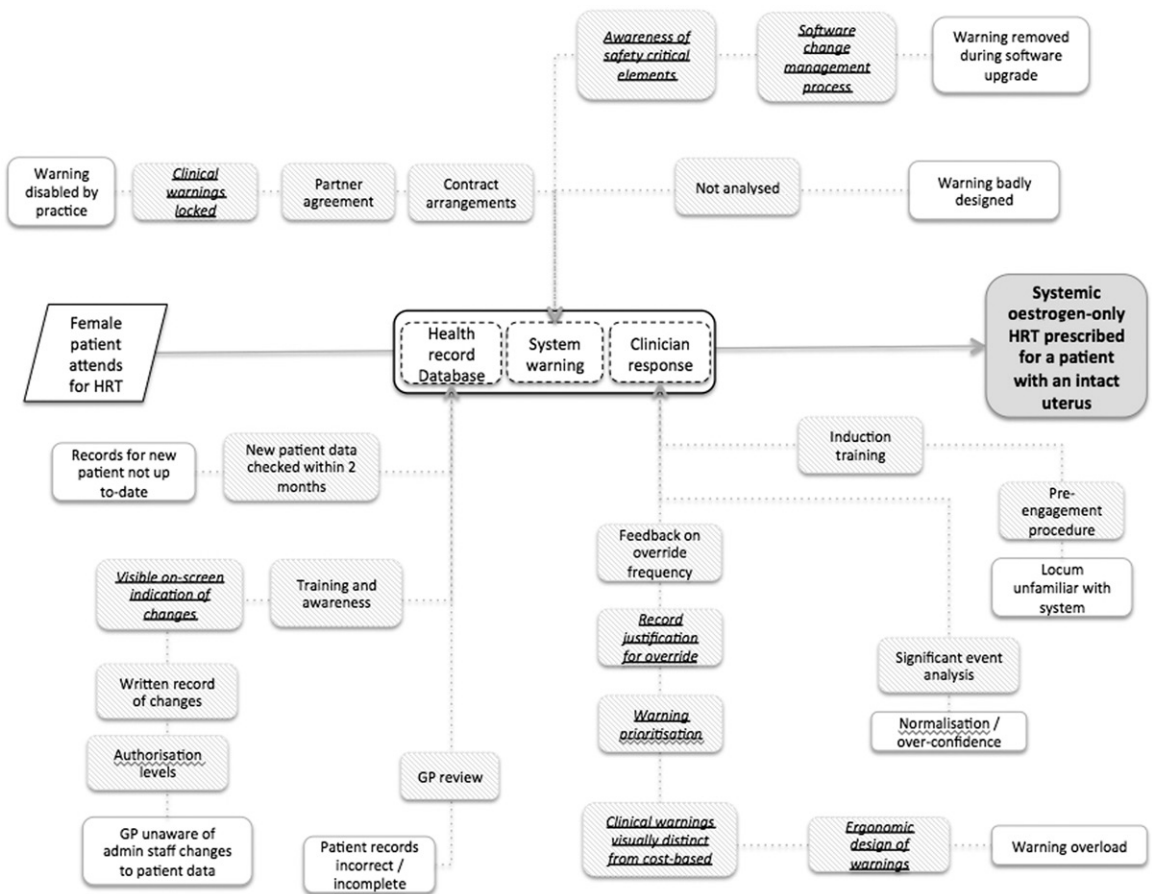


Figure 4. Summary of degradation factors and their safeguards for the barrier 'Use of Electronic Patient Records System'. (Note: Safeguards that are underlined and in italics are aspirational: they are possible but do not currently exist.)

- Attendees also thought they had developed a better appreciation of how the risk of the selected never event is currently managed.
- All of the attendees thought the time and effort needed to conduct the analysis was worthwhile (while recognizing that the analysis was not completed in the time available).

Prioritizing safeguards

In total, across the three top-level barriers shown in Figure 2, over 50 different safeguards were identified as having a role in protecting against the selected never event. Of these, only four were identified as protecting against more than one degradation factor. The remaining safeguards were specific to protecting against an individual degradation factor.

This raises a major challenge of identifying where the primary healthcare system should most efficiently focus effort to provide the biggest impact in reducing risk of even the single never event analyzed. Expecting any general practice to actively manage such a large number of safeguards for a single relatively rare event would clearly impose an intolerable burden on the front line primary care system. A method was, therefore, developed that could be used following a BTA to identify where to most cost-effectively focus effort to achieve the greatest improvement in the protection provided by the identified barriers and safeguards. The method is referred to as a 'Practicality \times Impact Assessment'.

Table 2. Summary of data generated in Bowtie Analysis for the barrier 'Electronic Patient Records System'.

Barrier	Elements	Degradation factors	Responsibility ³	Safeguards
Electronic Patient Records System: IT-based system that holds patient records. Barrier includes alarms and prompts advising user of potential risks, as well as clinician response to alarms.	Health records database	GP unaware of admin staff changes to patient records	Practice manager	Procedure and authorization levels Written record of change Visible on-screen indication of change/removal Training and awareness New patient checked within 2 months GP review
		Records for new patient not up to date	Practice manager	
		Patient records incorrect or incomplete	GP	
	System warnings	Warning disabled by practice	GP	Critical warnings locked in system Partners agreement Contract arrangements Communication of critical modifications Management of software change process Communication of changes to local practices
		Warning removed during software upgrade	NHS Board	
		Warning badly designed		Not analyzed
	Clinician response	Warning overload	NHS Board	Design of warning system Clinical warnings distinguished from cost-based warnings Warning prioritization Record of justification for ignoring Reflection on feedback of frequency of overrides
			GP	
		Normalization/overconfidence	Clinician ⁴	Significant event analysis and clinical practice audits (or other quality improvement initiatives)
		Locum unfamiliar with practice IT system	Practice manager Locum	Locum induction training Locum's preparation pre-engagement

Practicality × *Impact* assessment

The suggested Practicality and Impact method involves three steps as follows:

- For each of the identified degradation factors, identify the level in the organizational structure (i.e. local practice, regional Health Board, NHS Scotland) that would be expected to take responsibility for ensuring that factor does not actually lead to failure of the associated barrier (or its elements).
- At that organizational level, assess the safeguards associated with each of the degradation factors in terms of (a) the *Practicality* of taking action to either ensure that the identified safeguards is in place, or to introduce some other form of control that would provide the level of assurance sought, and (b) the expected *Impact* that taking the identified action would be likely to have. The assessment of *Practicality* and *Impact* can be carried out by reviewing the eight factors shown in Table 3. In each case, a decision made about which of the following statements applies:
 - Agree (score 5)
 - Somewhat agree (score 4)
 - Not sure (score 3)
 - Somewhat disagree (score 2)
 - Disagree (score 1).

Table 3. Practicality and Impact statements.

Practicality		Weighting
Ease of implementation	There are simple actions that are easily defined and can be implemented at this organizational level with little effort.	1
Resources	Little capital or resource requirement	1
Stakeholders	Few stakeholders who are under the direct command of the individual responsible for the safeguard.	1
Change Impact	Requires little change from existing practice	1
Scope	The action would also improve other controls or protect against other adverse events	1
Exposure	Opportunities for the degradation factor to act across other threats are frequent and arise in many different situations with many different people	1
Effectiveness	There is confidence that the action would be effective and would have an impact quickly	1
Risk reduction achieved	The degradation factor is widely recognized as a risk that is not currently adequately controlled.	1

Note that Table 3 shows a suggested weighting factor associated with each of the statements. In the absence of clear evidence or rationale to weight any of the factors higher than others, the weightings have all been assigned a default value of 1. In principle, however, it would of course be possible to use the weightings to reflect differential priorities of each of the factors, where a rationale for such relative weightings existed. By taking the product of the score associated with the level of agreement and the weighting factor for each factor, and summing across all four factors for that dimension, a single value can be achieved representing the relative assessed Practicality and Impact of taking action at the assigned organizational level to ensure each safeguard is in place.

3. Review the assessed *Practicality* and *Impact* scores across all of the degradation factors assigned to that level of the organization. Safeguards where both the *Practicality* and the *Impact* are assessed as being high are those that should be prioritized for action.

Evaluation of Practicality \times Impact ratings

To evaluate the usefulness of the Practicality \times Impact method, a second workshop was convened, attended by two of the same GPs, as well as one of the patient safety researchers who took part in the original workshop. For the purpose of evaluation, the method was only applied to the degradation factors and safeguards for the barrier 'Electronic patient records system'. Table 4 shows the consensus opinions reached for these assessments.

Eight degradation factors were analyzed, comprising 20 different safeguards. To make the P \times I assessments it was found convenient in a few cases to group the safeguards and to evaluate them as a single potential intervention. For example, as shown in Table 4, the safeguards associated with the degradation factor 'patient records incorrect or incomplete' were organized into two groups.

Consideration of Figure 5 suggests that the most effective steps that could be taken to reduce the risk profile and increase the strength of the barriers – in terms of being both practical and having reasonable impact – would be achieved by implementing safeguards A and B, i.e.

A: Procedure and authorization level; training and awareness.

B: New patient records checked within 2 months.

Action to implement safeguards 'C' (Clinician review of records in the presence of the patient) and 'E' (Critical warnings locked in system – under local IT control) were assessed as being the most practical measures that could be taken. The assessed Impact, however, was relatively low (with scores of 11 and 13, respectively, out of a maximum of 20).

Table 4. Assessments of Practicality and Impact of implementing safeguards to manage risk from degradation factors identified for the barrier 'Electronic Patient Records System'.

Degradation factor	Safeguards	Practicality				Impact			
		Effort	Resources	Stakeholders	Change	Scope	Exposure	Effectiveness	Risk reduction achieved
GP unaware of admin staff changes to patient records Records for new patient not up to date Patient records incorrect or incomplete	A: Procedure and authorization level; training and awareness	Agree	Somewhat agree	Agree	Agree	Agree	Agree	Somewhat agree	Somewhat agree
	B: New patient records checked within 2 months	Agree	Somewhat agree	Agree	Agree	Agree	Agree	Agree	Agree
	C: Clinician review of record in presence of the patient	Agree	Agree	Agree	Agree	Disagree	Disagree	Somewhat agree	Agree
	D: Significant event analysis and clinical practice audits (or other Quality Improvement initiatives)	Somewhat agree	Somewhat agree	Agree	Somewhat agree	Not sure	Disagree	Not sure	Agree
Warnings disabled by practice	E: Critical warnings locked in system (assuming local IT admin control)	Agree	Agree	Agree	Agree	Disagree	Somewhat disagree	Agree	Agree
	F: Critical warnings locked in system (assuming software change needed)	Disagree	Disagree	Disagree	Disagree	Disagree	Somewhat agree	Agree	Agree
	G: Partner agreement	Somewhat agree	Somewhat agree	Agree	Agree	Disagree	Somewhat agree	Agree	Agree
	H: IT contract arrangements between Practice and NHS Board	Disagree	Disagree	Disagree	Disagree	Disagree	Agree	Agree	Agree
Warning removed during software upgrade Warning overload	I: Design; distinguishing warnings; prioritization	Disagree	Not sure	Disagree	Disagree	Agree	Somewhat agree	Agree	Agree
	J: Record of justification	Disagree	Not sure	Disagree	Disagree	Agree	Agree	Agree	Agree
	K: Reflection on feedback of frequency of overrides	Agree	Disagree	Agree	Disagree	Disagree	Agree	Disagree	Agree
	L: Significant event analysis and clinical practice audits (or other Quality Improvement initiatives)	Somewhat agree	Somewhat agree	Agree	Not sure	Somewhat agree	Agree	Disagree	Agree
Normalization/over-confidence	M: Locum induction	Agree	Somewhat agree	Agree	Agree	Disagree	Somewhat disagree	Somewhat disagree	Somewhat agree
	N: Locum's preparation pre-engagement	Disagree	Agree	Somewhat agree	Disagree	Disagree	Somewhat disagree	Somewhat disagree	Somewhat agree

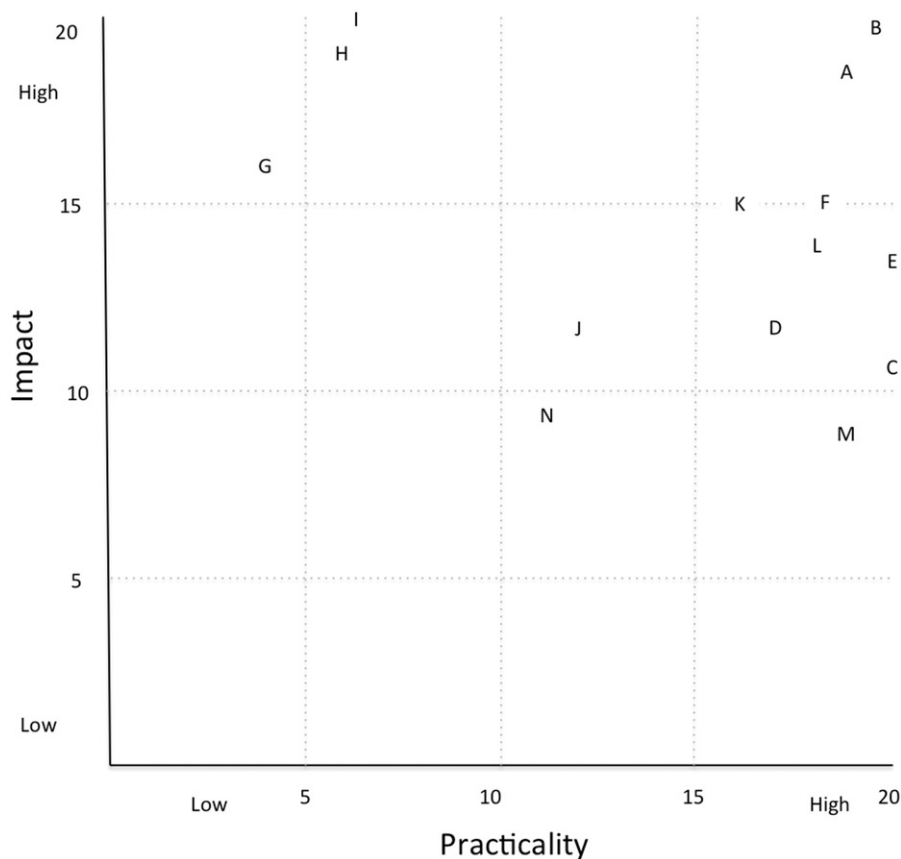


Figure 5. Practicality \times Impact plot for the degradation factors associated with failure of the barrier 'Electronic Patient Records System'. (Note: See the 'safeguards' column in Table 3 for the safeguard associated with each letter in the figure.)

In contrast, while taking action to improve the design and implementation of automated warnings within the patient electronic record system (safeguard I) was assessed as having the highest Impact (Impact score =20), it was considered as having low Practicality (Practicality score =6), due to the many organizational and bureaucratic issues, stakeholders, and commercial arrangements that would be involved in implementing the necessary change.

Finally, Figure 3 indicates that relying on locums to ensure they have fully prepared themselves for work in a new GP practice (safeguard N) was considered to be both the least practical measure while probably having the lowest impact in reducing risk. Note that consideration of the Practicality and Impact of implementing safeguards does not necessarily ensure that measures will be in place to protect against all of the identified degradation factors.

Limitations

Although the feedback supported the expectation of the benefits that BTA could potentially bring as a means of prospectively assessing risk in primary healthcare, there are a number of important limitations to the workshop as follows:

- The workshop was exploratory in nature, rather than being a controlled evaluation: it is possible, for example, that the results were influenced by the experience and interests of those who took part.

- The workshop involved a small number of attendees selected based on self-expressed interest and availability: there is no reason to believe they are representative of their respective professional groups as a whole.
- The study was led by an external facilitator. NES recognizes that relying on external specialists is not a viable option for any prospective risk analysis method to be used in healthcare in the long term. An essential pre-condition for any method that could be considered for widespread use is that an analysis can be conducted to an acceptable standard of quality by analysts drawn from the existing health community without imposing excessive demand on time and resources. (Note: NES is currently undertaking a study to explore the training, support, and resources needed to enable existing healthcare practitioners to carry out BTA without external facilitation.)

The workshop was limited to approximately 3 hours of analysis time. In that time it was not possible to complete a full BTA of the selected never event. It was estimated that in the order of 10–12 hours analysis time would have been needed to conduct an analysis of the selected never event that could be considered in some sense complete. That can be compared with the 32 meetings held over a 2-year period reported by Abdi et al. (2016) to assess five hazardous situations in intensive care, and the total of 18 hours in each of two hospitals (9×2 -hour meetings in each) reported by Wierenga et al. (2009) to assess 3 top events associated with the administration of medication.

Conclusions

There is a widespread interest in the healthcare community in implementing practical approaches to prospectively identifying and managing risk to patient safety. However, despite various studies and sources of guidance, till date few approaches to prospective risk assessment have been demonstrated to be practical for use in a primary healthcare context.

The technique of BTA is in widespread use in the traditional high-hazard industries as a means of identifying and communicating the barriers that are expected to be in place to defend against the occurrence of major incidents. Although there have been a number of published studies of the application of BTA to healthcare, none of them have been carried out in accordance with what is now recognized as best practice in the use of the method. In particular (i) no previous study has attempted to rigorously apply the quality criteria that high-hazard industries consider are necessary for a control to be recognized as a full ‘barrier’ capable of preventing incidents, and (ii) no previous studies has attempted to explore in any detail how identified barriers can be degraded, or what needs to be in place to prevent such degradation and to ensure barriers are as effective as they can reasonably be.

An exploratory workshop conducted for NES, conducted in accordance with recent statements of industry best practice, concluded that BTA has the potential to be applied to serious significant events in primary healthcare. The method could potentially have wider relevance as an approach to prospective risk analysis at all operational levels in the National Health Service.

Bowtie Analysis appears conceptually simple and relatively easy to implement, although some of the terminology and concepts may not be intuitively clear to the healthcare community. Importantly, the method need make no assumptions about the nature and causes of major incidents in a healthcare context. Having identified threats that could lead to loss of control over potentially hazardous situations, BTA:

- I. Identifies controls that can contribute to preventing the threat from leading to the unwanted events;
- II. Evaluates those controls to determine whether they are of sufficient quality to be considered as barriers;
- III. Investigates how those barriers can be defeated or degraded, and what needs to be in place to prevent such degradation.

There are concerns about the level of training, support, and resources that would be required for the healthcare community to be capable of conducting BTA to an adequate quality standard without having to rely on external facilitators. These concerns are currently being investigated by NES. When it is done properly, however, BTA appears to offer the potential to generate a rich understanding of the controls that need to be in place to protect against major adverse health events, and how they need to be implemented, supported, and managed.

Notes

1. Sometimes controls on the left-hand side are referred to as 'prevention controls', whereas those on the right-hand side are referred to as 'mitigation controls'.
2. CCPS (2018) uses the term 'degradation factor controls'.
3. Practice partners are always ultimately accountable. Responsibilities are delegated under the overall authority of the partners.
4. 'Clinician' can include Practice nurse, pharmacist, GPs

Disclosure statement

No potential conflict of interest was reported by the authors.

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